

REMARKS

Claims 16-18, 28-30 and 60-68 are currently under examination and have been rejected. Claims 60-64 have been canceled. No claims have been amended.

Claim Rejection Based on 35 U.S.C. 112

Claims 16-18 were rejected under 35 U.S.C. 112, first paragraph, for failing to meet the enablement requirement. The rejection contends that the specification does not provide clear indication that an increase in SEQ ID NO: 1 expression is indicative of a particular cancerous status of a cell.

Claims 28-30 were also rejected under 35 U.S.C. 112, first paragraph, for failing to meet the enablement requirement.

Applicants previously amended claim 16 to recite use of SEQ ID NO: 1 and claim 28 to recite detecting cancer using the polynucleotide of SEQ ID NO: 1, arguing that the data of Example 2 provide a correlation for breast tumor. Applicants have added new claim 63 drawn to a breast cell.

The Examiner has reiterated this ground of rejection on grounds that "it is unclear how one skilled in the art could reasonably make a conclusion that a cell is cancerous based on the detection of increased expression of TRIP13, when the data shows that TRIP13 has normal expression in most of the tumor samples." (see Office Action at page 3, lines 7-10)

In response, Applicants note that the data of Table 3 (at page 39) show clear correlation between the cancerous state and the increased copy number (i.e., increased expression) of TRIP13.

The Examiner correctly observes that the "normal" in Table 3 refers to normal TRIP13 expression and not to normal cells. However, what is being detected by the claimed method is increased expression of TRIP13.

TRIP13 expression was elevated in cancerous cells (although not in all of the samples) but was NOT elevated in normal cells, as taught in the Application at page 2, line 28, over to page 3, line 3, disclosing that TRIP13 is both amplified and over-expressed in cancerous but not in otherwise normal cells (also see page 19, lines 31-32, and at page 23, lines 12-13).

Thus, to answer the Examiner's above-quoted statement, one skilled in the art would reasonably conclude that a cell is cancerous if there is an increase in expression of TRIP13 (because Applicants report (in Table 3) some false negatives but not false positives). In short, if TRIP13 is elevated (especially by increased copy number) then the cell is cancerous – if TRIP13 is not elevated, then the clinician can do additional testing.

Put differently, normal TRIP13 does not prove the cell is normal but elevated TRIP13 shows it is cancerous. The claims are drawn to detecting elevated TRIP13. Elevated TRIP13 shows cancer and that is all the claims require.

Consequently, Applicants respectfully contend that claims 16 and 28 (and claims dependent thereon) are enabled (along with claims 65 and 66).

In view of the above amendments and remarks, Applicants believe that this ground of rejection has been overcome and respectfully request that this ground of rejection be withdrawn.

Claims 60-64 were rejected under 35 U.S.C. 112, paragraph 2, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In response, Applicants have canceled claims 60-64.

Claim Rejection Based on 35 U.S.C. 102

Claims 60-62 and 64 were rejected under 35 U.S.C. 102 as being anticipated by Dai et al (US 2003/0224374, filed 14 June 2002), which teaches a method of detecting cancer in a sample from a patient showing an increase in expression of a gene that encodes the amino acid sequence of Applicants' SEQ ID NO: 7. The reference does not disclose SEQ ID NO: 1 *per se*.

In response, Applicants have canceled claims 60-62 and 64.

Claims 60-62 and 64 were rejected under 35 U.S.C. 102 as being anticipated by Mutter et al (US 6,703,204, filed 27 July 2001), which teaches a method of detecting cancer in a sample from a patient showing an increase in expression of a gene that encodes the amino acid sequence of Applicants' SEQ ID NO: 7. The reference does not disclose SEQ ID NO: 1 *per se*.

In response, Applicants have canceled claims 60-62 and 64.

Claims 60-62 were rejected under 35 U.S.C. 102(b) as being anticipated by Aziz et al. (WO 02/086443), which teaches a method comprising detecting cancer in a sample from a patient showing an increase in expression of a gene corresponding to a polynucleotide that encodes a polypeptide having the amino acid sequence of

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Applicants' SEQ ID NO: 7 but does not teach the detection of a disposition toward developing cancer.

In response, Applicants have canceled claims 60-62.

Applicants include herewith the attached Request for Continued Examination and Request for 3 month extension of time along with the required fees. No additional fees are believed due. Applicants request that the Commissioner charge any additional fee for this correspondence, or credit any overpayment, to Deposit Acct. No. 03-0678.

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Alan J. Grant
Alan J. Grant , Esq.

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Date

Respectfully submitted,

Alan J. Grant

Alan J. Grant, Esq.
Reg. No. 33,389

CARELLA, BYRNE BAIN, GILFILLAN,
CECCHI, STEWART & OLSTEIN
5 Becker Farm Road
Roseland, NJ 07068
Phone: 973-994-1700
Fax: 973-994-1744